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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,660	09/28/2006	Satoshi Amano	27563U	9713

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
06/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,660	AMANO ET AL.	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-15* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicants' election filed 04/23/2020; and IDS filed 07/28/2006.

Claims 7-15 are pending.

Response to Election/Restrictions

1. Applicant's election of invention I, species "2-isopropoxyethoxymethy" and "styrene-based block copolymer", claims 7-14, in the reply filed on 04/23/2010 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was considered as made **without** traverse in the reply filed on 4/23/2010. Although claim 15 is amended to include all of the elements that correspond to the product claim 7 of group I, however, group I includes more limitations recited by claims 8-14 that not required by group II. Further the package of group I can be used in materially different method such as simply for protection from environment during

storage as evident by US 7,220,473, col.7, line 64 till col.8, line 20 and figure 6. Package of the patch of invention I not necessary used to inhibiting migration of drugs to the packaging material as required by group II. The prior art that anticipates or make obvious one group may not anticipate or make obvious the second group. Therefore, claim 15 remains withdrawn, however, rejoinder practice will be applied should the product of group I found allowable.

Claims 7-14 are included in the prosecution.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

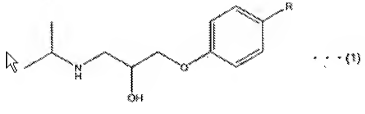
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 7-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al. US 6,905,016, currently listed on PTO 892, in view of JP 2003-313122 ('122), currently provided, or *vise versa*, JP '122 in view of Kanios.

Applicant Claims

Applicant currently amended claims 7 recites a patch-containing pouch housing in its interior a patch which has a pressure-sensitive adhesive layer laminated on at least one side of a support and has a release film attached to said pressure-sensitive adhesive layer, wherein said pressure-sensitive adhesive layer contains a drug represented by general formula (1)



(1)

or a pharmaceutically acceptable salt thereof, wherein R represents 2-isopropoxyethoxymethyl, carbamoylmethyl or 2- methoxyethyl, and wherein at least a portion of the inner surface of said pouch in contact with said patch is made of polyacrylonitrile.

The claimed compound is bisoprolol.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

Kanios teaches package for transdermal system to prevent and control degradation reactions that resulting from contamination of active material with packaging materials and improves stability of the drug during storage prior to use (abstract; col.3, lines 58-67; col.4, lines 18-22). The package material is inert to the component of the transdermal system (col.4, lines 27-30). Figure 1 shows the package material is multi-layered including layer 11 the innermost layer adjacent to the transdermal system and layer 12 the outermost layer distant from the transdermal system. The preferred packaging material for layer 11 does not react with or otherwise adversely affect the drug or other components of the transdermal system. Preferred material for layer 11 is acrylonitrile. Preferred material to layer 12 is polyester or laminate comprising Mylan polyester and aluminum foil, Mylan is polyethylene terephthalate. (See col.6, lines 21-67). Active agents suitable for delivery by the packaged transdermal system includes propranolol (col.8, line 45).

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Although Kanios teaches propranolol as active agent suitable for transdermal system, however, Kanios does not teach bisoprolol as instantly claimed by claim 7, or the adhesives claimed by claim 8.

JP '122 teaches patch to deliver bisoprolol transdermally comprising adhesive layer containing bisoprolol or its pharmaceutically acceptable salts, support layer and release liner (abstract; paragraph 0023, 0032). The adhesive is acrylate-based adhesive including acrylic acid that has increased release of the drug from the adhesive and high percutaneous absorption for prolonged period with reduced irritation and residue on the skin (paragraphs 0005, 0007-0011). Bisoprolol is highly selective β_1 receptor antagonist and effective to treat essential hypertension and angina and to improve arrhythmia (paragraph 0002).

Finding of Prima Facie Obviousness Rational and Motivation

(MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a package for a transdermal system comprising innermost layer of acrylonitrile and outermost layer of polyethylene terephthalate as taught by Kanios wherein the patch used to deliver propranolol, and replace propranolol with bisoprolol in adhesive comprising acrylic acid as taught by JP '122. One would have been motivated to do so because JP '122 teaches that bisoprolol is highly

selective β_1 receptor antagonist and effective to treat essential hypertension and angina and to improve arrhythmia, and one would have used acrylic acid based adhesive taught by JP '122 because JP '122 teaches that such adhesive has increased release of the drug from the adhesive and high percutaneous absorption for prolonged period with reduced irritation and residue on the skin. One would reasonably expect formulating transdermal system comprising acrylic acid-based adhesive layer containing bisoprolol wherein the patch is packaged in a multilaminate package having the innermost layer of acrylonitrile and outermost layer of polyethylene terephthalate, and wherein the patch is stabilized during storage, provides high drug release and skin absorption for long period during use and effectively treat essential hypertension and angina and to improve arrhythmia.

Vise versa, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal patch to deliver bisoprolol comprising acrylic acid-based adhesive layer containing bisoprolol, support layer and release liner as taught by JP '122, and further pack the patch in the multilaminate package taught by Kanios comprising innermost layer adjacent to the transdermal system made of polyacrylonitrile and outermost layer distant from the transdermal system made of polyethylene terephthalate. One would have been motivated to do so because Kanios teaches such a package prevents and controls degradation reactions that resulting from contamination of active material with packaging materials and improves stability of the drug during storage prior to use. One would reasonably expect formulating stable transdermal system comprising acrylic acid-based adhesive layer containing bisoprolol

wherein the patch is packaged in a multilaminate package having the innermost layer of acrylonitrile and outermost layer of terephthalate, and wherein the patch is protected against degradation reactions that resulting from contamination of active material with packaging materials.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

7. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kanios and JP '122 as applied to claims 7-12 above, and further in view of JP 07-132946 ('946), English abstracts has been provided by IDS filed 07/28/2006 and a translation of the entire documents is currently provided by the examiner.

Applicant Claims

Applicants' claims 13 and 14 further recite an aluminum foil between the polyacrylonitrile layer and the polyethylene terephthalate layer of the packaging material.

Determination of the Scope and Content of the Prior Art

(MPEP §2141.01)

The combined teachings of Kanios and JP '122 are previously discussed in this office action.

However, the combination of the references does not teach the aluminum foil between the innermost and outermost layers of package as instantly claimed by claims 13 and 14.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

JP '946 teaches packaging for cataplasm using packaging material comprising innermost layer of polyacrylonitrile, outermost layer of polyethylene terephthalate wherein the innermost layer and outermost layer are combined with an aluminum foil layer (paragraphs 001, 004, 0013). The packaging prevent adsorption of active agent to the package and does not cause fall in the drug effect (paragraphs 0014, 0015).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide transdermal system comprising bisoprolol packaged in a multilaminate package having the innermost layer of acrylonitrile and outermost layer of terephthalate as taught by the combination of Kanios and JP '122, and further add aluminum foil layer between the innermost and outermost layer as taught by JP '946. One would have been motivated to do so because JP '946 teaches that such a

multilaminate package prevents adsorption of active agent to the package and does not cause fall in the drug effect. One would reasonably expect formulating transdermal system comprising bisoprolol and packaged in a multilaminate package having innermost layer of polyacrylonitrile layer that is combined with an outermost layer of polyethylene terephthalate by an aluminum foil layer wherein the drug is stabilized.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Isis A Ghali/
Primary Examiner, Art Unit 1611

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